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EXAMINER	
KRSEK, STAPLES, J	
ART UNIT	**PAPER NUMBER**
1813	6

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DATE MAILED: 12/22/93

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

Election

☐ This application has been examined ☑ Responsive to communication filed on 10-27-93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 1-8 are pending in the application.
   Of the above, claims 3-8 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 1-2 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

Applicant's election without traverse of Group 1, claims 1 and 2, drawn to vaccine products and production methods in Paper No. 5 is acknowledged. Claims 3-8 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

This application is a continuation in part of 07/744,649. Because the specification of the parent application does not appear to support the use of Recognin as a cancer vaccine, June 16, 1993 is considered to be the effective filing date of this application.

Although the figures are described throughout the specification, it is suggested that a separate section entitled "Brief Description of the Drawings" be included in the specification on p. 6 before the section entitled "Example 1".

The attempt to incorporate subject matter into this application by reference to the U.S. Applications on p 17 is improper because essential material may only be incorporated by reference to a United States patent or an allowed U.S. application. Essential material may not be incorporated by reference to non-patent publications. See M.P.E.P. 608.01(p).

Claims 1 and 2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a process, but does not contain a positive method step. Note Ex parte Erlich 3, USPQ2d 1101:

"Method claims need not recite all operating details but should at least recite positive, active steps so that claim will set out and circumscribe particular area with reasonable degree of precision and particularity and make clear what subject matter claims encompass, as well as make clear subject matter from which others would be precluded."

The claim language reads "A process for producing and administering a vaccine...". An example of a method step would be "A process to inhibit or to destroy cancer cells...comprising administering a vaccine.

In claim 2, the phrase "will cause to be inhibited or destroyed cancer cells, regardless of cell type," is confusing. Rearrangement of the phrase to read "will cause cancer cells, regardless of cell type, to be inhibited or destroyed" is suggested.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure. The specification teaches that Recognin is present in several cell types of malignancy

by immunostaining using anti-Recognin antibodies (p 7). The specification also teaches that anti-Recognin antibodies inhibit the growth of small lung carcinoma cells *in vitro* (p 12-13). The specification also discloses that levels of anti-Recognin antibody in humans increase with age and are increased in patients with breast cancer (p 15). The specification does not teach that Recognin, when administered as a vaccine, prevents or treats clinical cancer. Because patients diagnosed with cancer already have increased serum levels of anti-Recognin antibodies, as disclosed in the specification, it is not predictable whether enhancing these antibody levels by administering a Recognin vaccine would be effective in treating the cancer. In addition Stevenson discloses that vaccination against cancer poses other problems such as the selection of a suitable adjuvant for use in humans (p2256, column 1). Therefore, in the absence of clinical data or an appropriate animal model, one of ordinary skill in the art could not predict if the claimed vaccine would sufficiently increase the levels of anti-Recognin antibodies to prevent or treat cancer in humans.

Claims 1 and 2 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1 and 3 are rejected under 35 U.S.C. § 101 because the invention as disclosed is inoperative and therefore lacks patentable utility. The invention is directed toward a Recognin protein vaccine to prevent or treat cancer. The specification fails to establish utility of the claimed vaccine for preventing the development of cancer or treating cancer in humans for the reasons discussed above in the rejected under 35 U.S.C. § 112, first paragraph.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Cantrell.

Cantrell teaches processes for the preparation of vaccines for use in the treatment and prevention of tumors (column 2, line 66, and column 16, line 59 to column 17, line 1).

Claim 1 is rejected under 35 U.S.C. § 102(e) as being anticipated by Rapp.

Rapp teaches the preparation and administration of a vaccine used to treat cancer (column 2, lines 10-23, paragraph bridging columns 2 and 3).

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 2 is rejected under 35 U.S.C. § 103 as being unpatentable over Cantrell or Rapp in view of Bosgoch et al and Bosgoch et al.

Cantrell teaches the use of tumor associated antigens as vaccines to prevent or treat cancer (column 2, line 66). Rapp teaches the administration of oncoproteins induce an anti-oncoprotein immune response to neutralize cancer (column 2, lines 10-23). Rapp et al also teaches that oncoproteins are often immunogenic in their natural host and their presence on tumor cells renders the antigen presenting cells susceptible to immune surveillance (column 1, lines 30-35). Neither Cantrall nor Rapp teach the use of Recognin as a cancer vaccine.

Bosgoch et al (1980) teach that Recognin is a tumor associated antigen (p 409, paragraph 1). Bosgoch et al (1991) teach that Recognin is an oncoprotein (column 1, paragraph 3). It would have been obvious to one of ordinary skill in the art to use Recognin as a vaccine to treat or prevent cancer because both tumor associated antigens and oncoproteins can be used as tumor vaccines, as taught by Cantrall and Rapp, and because Recognin is both a tumor associated protein and an oncoprotein, as taught by Bosgoch et al, one of ordinary skill would expect that Recognin could also be administered to induce and anti-Recognin immune response to neutralize cancer.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Krsek-Staples whose telephone number is (703) 305-7556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission via the PTO Fax Center, located in Crystal Mall 1. The Fax Center number is (703) 308-4227. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180

JKS
Julie Krsek-Staples, Ph.D.
December 20, 1993